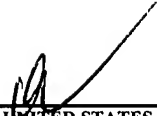




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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,741	09/19/2003	Kazuko Shinozaki	382.1029DIV1	5801

23280 7590 09/20/2007
DAVIDSON, DAVIDSON & KAPPEL, LLC
485 SEVENTH AVENUE, 14TH FLOOR
NEW YORK, NY 10018

EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

MAIL DATE	DELIVERY MODE
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09/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/664,741

Applicant(s)

SHINOZAKI ET AL.

Examiner

David H. Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

STATUS OF THE APPLICATION

1. This Office action is in response to the Remarks filed on 28 June 2007.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102/103

3. Claims 5-8 remain rejected and new claims 9-12 are under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent 6,417,428 B1, Thomashow *et al* (filed 23 November 1998, claiming priority as a continuation-in-part to U.S. Application 09/017,575 filed on 3 February 1998). This rejection is repeated for the reason of record as set forth in the last Office action mailed 27 March 2007. Applicant's arguments filed 28 June 2007 have been fully considered but they are not persuasive. This rejection has been modified from that of the previous Office action.

Thomashow *et al* disclose a method of altering an environmental stress response of a plant by providing a recombinant molecule comprising a polynucleotide that encodes a polypeptide that has the amino acid sequence of Applicants' SEQ ID NO: 6, at claim 11 (SEQ ID NO: 2). Thomashow *et al* disclose a transgenic plant transformed with polynucleotide operably linked to a promoter that is regulated by changes in environment conditions at claim 8. Thomashow *et al* discloses SEQ ID NO: 1 that encodes SEQ ID NO: 2, SEQ ID NO: 2 being identical to Applicants' SEQ ID NO: 6.

While SEQ ID NO: 1 of Thomashow *et al* is 94.1% identical to Applicants' SEQ ID NO: 6, it discloses an identical coding region. The differences between SEQ ID NO:

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1 of Thomashow *et al* and Applicants' SEQ ID NO: 5 does not appear to lead to a teaching of unexpected results since they are functionally equivalent.

Applicants argue that, as described on page 2 of the present application, "when a gene which induces the expression of a plurality of genes is introduced into a host plant (e.g., like in Thomashow *et al.*), the genes are activated at the same time. Applicants argue that as a result, the energy of the host plant is directed to production of the products of these genes and intracellular metabolism of such gene products, which often brings about delay in the growth of the host plant or dwarfing of the plant." (page 4, last paragraph of the Remarks). This argument does not appear to be relevant to the issue of anticipation or obviousness of the claimed structure.

Applicants argue that at the time of filing of this application, it was not known in the art what kind of promoters should be used for high level and stable expression of artificially introduced genes only when the plant is subject to the stress. Applicants argue that the inventors were the first to find and demonstrated that, e.g., the self-amplification mechanism, i.e., the use of a promoter comprising DRE region as presently claimed, is useful for producing stress resistant plants (page 5, 1st paragraph of the Remarks). This argument is not found to be persuasive. There is no requirement that a person of ordinary-skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. See *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) which teaches, "[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is

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enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.”.

Applicants argue that the use of the stress-responsive promoter (e.g., comprising DRE region(s) as presently claimed, enables, inter alia, DREB 1B gene to amplify itself in response to environmental stress (self-amplification). Applicants further argue that as a result of high level and stable expression of DREB 1B gene in a short period of time, the transgenic plant acquires stress resistance without dwarfing (page 5, 4th paragraph of the Remarks). This argument is not found to be persuasive for the reason given *supra*.

Applicants argue that Thomashow et al. describe nothing about the stress-responsive promoter comprising DRE region(s) as recited in the present claims. Applicants argue that, instead, Thomashow et al. describe a "tissue specific promoter" that is used to alter COR gene expression in tissues that are highly sensitive to stress and "a promoter that turns on at warmer temperature than the temperature at which the plant normally exhibits cold tolerance (See page 29 of Thomashow et al.). Applicants argue that the latter promoter means a promoter that is similar to a constitutive promoter, because this promoter can induce the gene expressions at warmer temperature than the temperature at which the plant normally exhibits cold tolerance (page 5, 5th paragraph of the Remarks). These arguments are not found to be persuasive. The test for adequacy of a prior art disclosure to anticipate or render claims obvious is not the same test as that for adequacy of a patent application disclosure to

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support claims under 35 U.S.C. § 112, as taught in *In re Hafner*, 161 USPQ 783, (CCPA 1969).

Applicants argue that Thomashow et al. states that "a strong constitutive promoter could be used to cause increased levels of COR gene expression in both non-stress and stressed plants which in turn, results in enhanced freezing and dehydration tolerance." Applicants argue that Thomashow et al. provide only a transgenic plant transformed with CBF 1 gene under the control of the strong constitutive promoter: cauliflower mosaic virus (CaMV) 35S promoter (See page 45, last paragraph of Thomashow et al.) as working examples of transgenic plants, however as discussed above, when a promoter such as CaMV35S which induces the expression of a plurality of genes is introduced into a host plant, the genes are activated at the same time. Applicants argue that as a result, the energy of the host plant is directed to production of the products of these genes and intracellular metabolism of such gene products, which often brings about delay in the growth of the host plant or dwarfing of the plant (See Example 4 of the present invention). Applicants argue that Thomashow et al. do not teach or suggest part a protein or a DNA "... operably linked downstream of a stress responsive promoter comprising DRE region(s)" as recited in the present claims. Arguments on page 6, 1st-3rd paragraph of the Remarks. These arguments are not found to be persuasive. There is no requirement that Thomashow *et al* had to reduce to practice a structure disclosed in the patent.

Applicants argue that Thomashow et al. teach away from the use of stress responsive promoter comprising a DRE region (e.g., to which said DREB 1 B protein can

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bind) as presently claimed (page 6, 5th paragraph of the Remarks). This argument is not found to be persuasive. Thomashow *et al* teach "In each of the above embodiments, expression of the recombinant copy of the regulatory gene may be under the control of the promoter. The promoter may increase the level at which the regulatory gene is expressed, express the regulatory gene without being induced by an environmental stress or express the regulatory gene in response to a different form or degree of environmental stress that would otherwise be needed to induce expression of the regulatory gene. For example, a strong constitutive promoter could be used to cause increased levels of COR gene expression in both non-stress and stressed plants which in turn, results in enhanced freezing and dehydration tolerance. A tissue specific promoter could be used to alter COR gene expression in tissues that are highly sensitive to stress (and thereby enhance the stress tolerance of these tissues). A promoter could be used which turns on at a temperature that is warmer than the temperature at which the plant normally exhibits cold tolerance. This would enable the cold tolerance thermostat of a plant to be altered. Similarly, a promoter can be used which turns on at a dehydration condition that is wetter than the dehydration condition at which the plant normally exhibits dehydration tolerance. This would enable the level at which a plant responds to dehydration to be altered. An inducible promoter could be used such that gene expression could be induced by application of an exogenous inducer (e.g., induce COR genes when a frost is imminent). This would enable stress tolerance to be induced externally by a grower whenever desired." (column 14, last paragraph).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

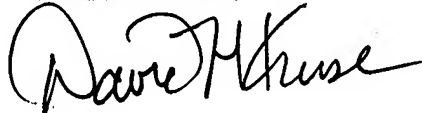
5. No claims are allowed.
6. This Office action is non-final to correct deficiencies in the rejection of record.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
14 September 2007

8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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